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Dräger Medical

Dräger

Operator's Instruction Manual

Part Number: 4114448-001
Rev: D
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NAD Omicron Monitor

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1 Introduction

This section introduces you to the North American Dräger (NAD) Omicron Monitor and describes how to use this manual.

Operator's Responsibility for Patient Safety

The NAD Omicron Monitor will perform as detailed in this manual, and on its accompanying label, when assembled, operated, maintained, and repaired according to the following instructions.

If your NAD Omicron Monitor needs to be repaired, contact your NAD service representative or contact NAD directly at the following address:

3122 Commerce Drive
Telford, PA 18969
Tel: (800) 543-5047

WARNING: The NAD Omicron Monitor should not be repaired or modified by any individual or entity other than NAD personnel or repair services authorized by NAD. Malfunctions resulting from damage due to improper use or alteration of the NAD Omicron Monitor are the sole responsibility of the user.

General Warnings, Cautions, and Notes

WARNING: Upon power up, the monitor will load the last saved alarm settings. These parameters may not be appropriate for the current patient's ventilatory status. The user must review these alarm parameters to determine their appropriateness for the current patient and adjust those settings as clinically necessary.

WARNING: If the NAD Omicron Monitor shows a reading of 127 cm H_2O or -127 cm H_2O, DO NOT CONTINUE TO USE THE UNIT IN CLINICAL SETTINGS. Remove the unit from use for servicing.

CAUTION: United States Federal Law restricts this device to sale by or on the order of the physician.

CAUTION: The NAD Omicron monitor has been designed to work only with the Narkomed MRI anesthesia machine. Use only NAD supplied oxygen and flow sensors with this monitor to ensure accuracy and compatibility with MRI systems.

NOTE: Due to the sensitivity of the monitor, and while monitoring within the Respiratory Volume display, a "00" may be occasionally observed on the Respiratory Volume display. The presence of the "00" does not influence the accuracy of data or alarms management, and the display will be updated with real-time Respiratory Volume data at the completion of the next expiratory phase.

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Flow Head Installation

This section instructs you on installing the flow head.

Flow Head Installation

Connect the flow head sensor to the monitor through the flexible triple lumen tubing. The flexible tubing mates with the monitor only one way, ensuring that each pressure port is connected correctly. The flexible tubing is labled “Toward Flow Head.” Ensure that the arrows on the tubing are pointing in the direction of the flow sensor. See Figure 2-1.

CAUTION: The NAD Omicron Monitor has been designed to work only with the Narkomed MRI anesthesia machine. Use only NAD-supplied oxygen and flow sensors with this monitor to ensure accuracy and compatibility with MRI systems.

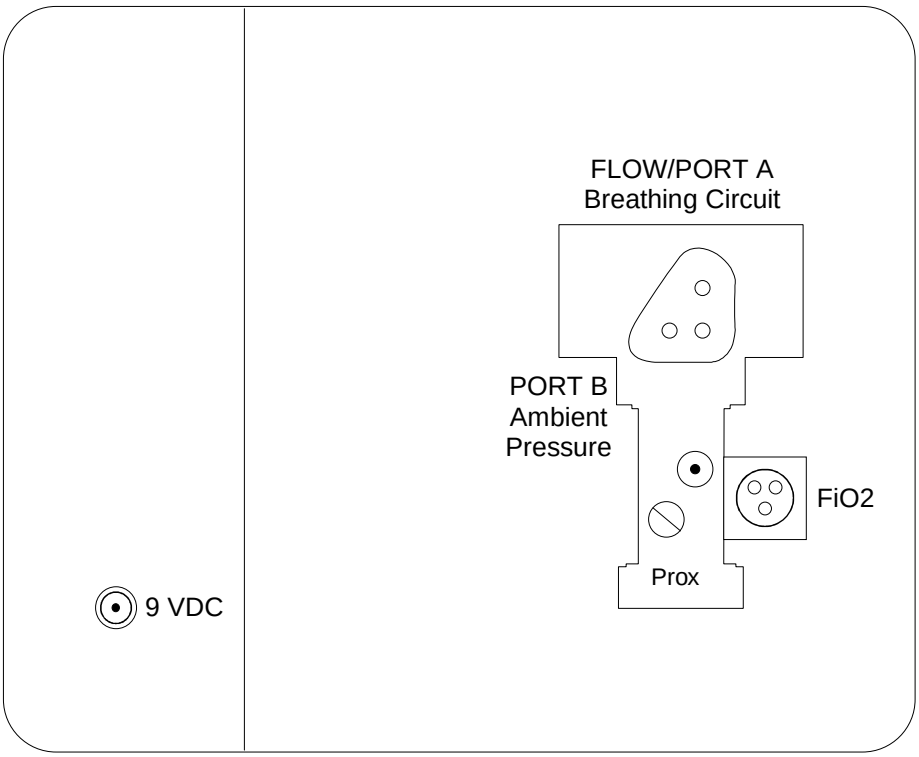

Figure 2-1. Rear Panel

The flow sensor is intended for use on patients with tidal volumes from 50 to 1500 milliliters. The flexible tubing transfers pressures within the sensor housing to ports on the monitor. The monitor uses these pressures to compute displayed values. The flexible tubing transfers two flow parameters (+ flow and - flow) and the pressure within the patient breathing circuit.

3

Operating Instructions

This section instructs you in how to use the NAD Omicron Monitor.

Real Time Pressure Bar Graph

A common feature of all data screens is the real time pressure bar graph. The bar graph represents the instantaneous pressure within the breathing circuit. If the pressure exceeds the limits of the display (more than 120 cm H_2O or less than -10 cm H_2O), the bottom or top segments will blink. The unit displays two stationary segments; one that corresponds to the high pressure alarm limit, and the other that corresponds to the low pressure limit.

Breathing Pressure Low Limit

The breathing pressure low limit setting serves two purposes. First, when the peak breathing pressure stays below the low limit for fifteen (15) seconds, the Pressure and Respiratory Rate displays will display dashes (---). Second, when the PEEP pressure stays above the low limit for fifteen (15) seconds, the continuous pressure alarm is annunciated.

User Input Keys

User input keys are grouped into three categories: display function keys, alarm function keys, and calibration function keys. See Figure 3-1.

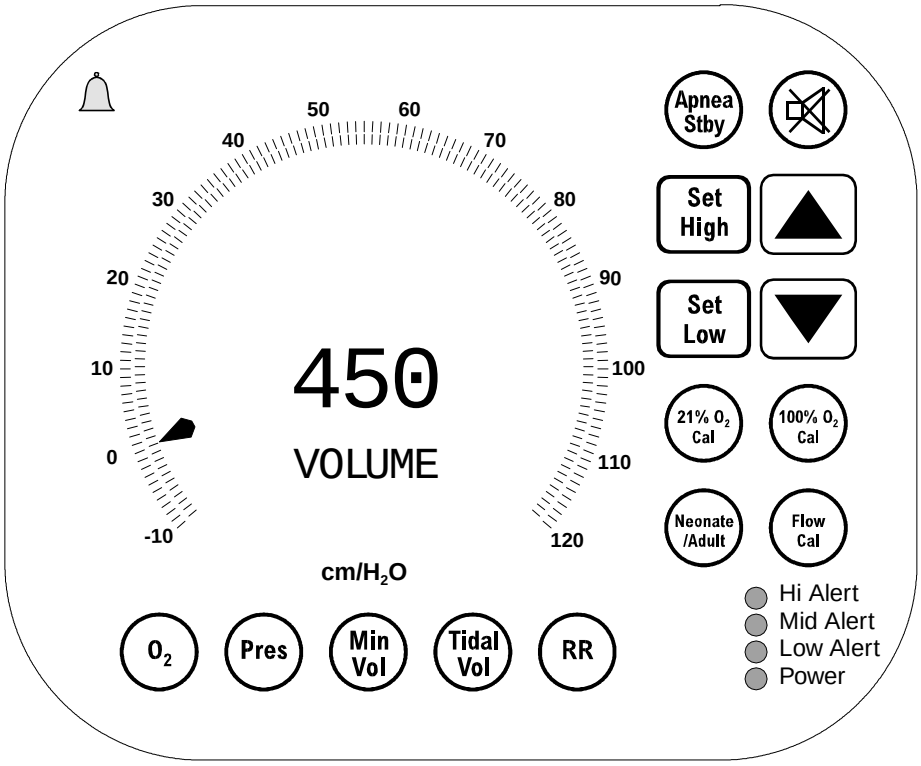

Figure 3-1. Front Panel

Display Function Keys

Use the following display function keys to operate the NAD Omicron Monitor.

O2

The O2 key is used to display the Inspiratory Oxygen screen. This is the first screen to appear on the monitor when you turn on the system.

You must calibrate the oxygen sensor before oxygen data is displayed. For greatest accuracy, you should complete the two-part calibration (first using 21% oxygen, then using 100% oxygen). After completing the first part (21% calibration), the monitor will display oxygen concentration, and it will also display LO O2 CAL to indicate that you have not performed the 100% oxygen calibration.

CAUTION: The characteristics of the oxygen sensor change gradually with time. To ensure accuracy, the oxygen sensor must be recalibrated before each day's use. If the oxygen sensor fails to calibrate, refer to "Troubleshooting" on page 5-1.

PRES

The Pres key is used to display the Breathing Pressure screen. The unit displays three digital values. The largest value represents the peak pressure recorded during the last breath. The other two values are smaller and are located below the peak pressure. The value to the left of the peak pressure represents the minimum, while the value to the right of the peak pressure represents the mean pressure during the last breath.

WARNING: If the NAD Omicron Monitor shows a reading of 127 cm H20 or -127 cm H20, DO NOT CONTINUE TO USE THE UNIT IN CLINICAL SETTINGS. Remove the unit from use for servicing.

MIN VOL

The Min Vol key is used to display the Minute Volume screen. The monitor computes this parameter from a running average of tidal volumes from the last four breaths, or 15 seconds, whichever is greater. It refreshes the display after each breath.

TIDAL VOL

The Tidal Vol key is used to display the Tidal Volume screen. Tidal volume is computed from expiratory flow and is updated after each breath.

RR

The RR key is used to display the Respiratory Rate screen. When computing respiratory rate, the monitor counts both machine breaths and the patient's spontaneous breaths.

NEONATE/ ADULT

The Neonate/Adult key will not invoke the neonatal mode of operation; the monitor is always in the adult mode of operation. Depressing this key will cause the high and low alarm limits for Tidal Volume and Minute Volume to revert back to the last user-saved or factory-preset alarm parameters (see Table 3-4 on page 3-7 for more information).

Alarm Function Keys

Clearing Alarms

None of the monitor's alarms is a latching type alarm. When an alarm condition exists, the monitor clears the alarm at the end of the next breath if the respiratory parameter falls within alarm limits during that breath.

SILENCE

Press this key to silence alarms for 120 seconds. During this interval,

- if the alarm condition continues,
  - the audible alarm remains off,
  - one of the color-coded LED visual alarm indicators (lower right-hand corner of the front panel) remains on, and
  - the red alarm status indicator (upper left-hand corner of the fnont panel) remains on.
- If the alarm condition exists longer than 120 seconds, the monitor turns the audible alarm back on.

APNEA STBY

Pressing the Apnea Stby key disables the pressure and volume apnea alarms. The volume apnea alarms are automatically enabled again as soon as the next breath is detected.

Setting Alarm Limits

Four Alarm Function Keys (High Limit, Low Limit, UP ARROW, DOWN ARROW) are used to change alarm limits for the five displayed respiratory parameters (Oxygen, Pressure, Minute Volume, Tidal Volume, or Respiratory Rate).

NOTE: All alarms are suspended while the monitor is in alarm limit setting screens.

Execute the following steps to view or change the alarm limit setting(s) for a specific respiratory parameter:

1. Press the parameter's display function key.
2. Use one of the following four keys:
   - HIGH LIMIT
     With the monitor set to a parameter's display screen or to the Low Limit Set screen, pressing the High Limit key opens the Set High Limit Alarm screen for that parameter.
   - LOW LIMIT
     With the monitor set to a parameter's display screen or to the High Limit Set screen, pressing the Low Limit key opens the Set Low Limit Alarm screen for that parameter. Unlike the High Limit Set screens, there are only four Low Limit Set screens.

NOTE: The Respiratory Rate parameter does not have a low limit set point.

– UP ARROW
With the monitor set to either the High Limit or Low Limit Set screen, press or press and hold this key to increase the alarm limit.

– DOWN ARROW
With the monitor set to either the High Limit or Low Limit Set screen, press or press and hold this key to decrease the alarm limit.

The monitor keeps track of how long it displays a parameter's High or Low Limit Alarm Set screen. After 15 seconds without additional user input, it automatically returns to the parameter's display screen.

Alarm Priority

Depending on the alarm urgency, the monitor issues three different priority alarms: high, middle, and low priority. The visual alarm indicator is color coded. If more than one alarm condition exists, the monitor shows the highest alarm priority.

The following tables list the alarm alert priorities:

Table 3-1. High Alert Priority Alarms

Display	Designation	Description
HI LIMIT	Pressure High Limit	Peak Pressure Value is above the High Limit Set Value.
APNEA VOL	Apnea Volume > 30 Sec	Tidal Volume is less than 30 mL for more than 30 seconds.
RATE ALRM	Respiratory Rate High Limit	Respiratory Rate is above the High Limit Set Value.
O2 LO LMT	O_2 Low Limit	O_2 Concentration is below the Low Limit Set Value.
CONT PR	Continuous Pressure	PEEP Pressure Value is above the Low Limit Set Value for more than 15 seconds.
TIDAL HI	Tidal Volume High Limit	Tidal Volume Value is above the High Limit Set Value.

Table 3-2. Middle Alert Priority Alarms

Display	Designation	Description
APNEA VOL	Apnea Volume > 15 sec	Tidal Volume is less than 30 mL for more than 15 seconds.
MINUT HI	Minute Volume High Limit	Minute Volume Value is above the High Limit Set Value.
TIDAL LOW	Tidal Volume Low Limit	Tidal Volume Value is below the Low Limit Set Value.
MINUT LOW	Minute Volume Low Limit	Minute Volume Value is below the Low Limit Set Value.

Table 3-3. Low Alert Priority Alarms

Display	Designation	Description
O2 HI LMT	O_2 High Limit	O_2 concentration is above the High Limit Set Value.
O2 SENSOR	O_2 Sensor Failure	O_2 Sensor failed or disconnected.

Saving Alarm Limits

When the monitor leaves the manufacturer's production facility, each alarm limit is set to the values listed in Table 3-4 (factory presets).

Each time the NAD Omicron Monitor is energized, the alarm limits are set to the last saved default values. Use this procedure to set the default values to the current alarm limit settings:

1. Select the parameter to be changed and depress the parameter keys.
2. Change the setting by pressing the high or low limit button and the up or down arrow keys.
3. Depress the parameter keys again (this will cause the numbers on the monitor to disappear).
4. Simultaneously press the up and down arrow keys until the monitor displays the message SAVE DATA; the alarm limit settings are saved.

Even when powered off, the monitor retains stored alarm limits.

NOTE: If the alarm limit settings for Tidal Volume and Minute Volume are not saved as described above, depressing the Neonate/Adult key will restore those alarm limits to the last user-saved or factory-saved preset alarm parameters (see Table 3-4 on page 3-7 for more information).

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Table 3-4. Factory Pre-set Alarm Limits

Alarm	Alarm Limit
O2 High Limit	100%
O2 Low Limit	30%
Pressure High Limit	50 cm H_2O
Pressure Low Limit	12 cm H_2O
Minute Volume High Limit	10 L
Minute Volume Low Limit	1 L
Tidal Volume High Limit	1200 mL
Tidal Volume Low Limit	200 mL
Respiratory Rate High Limit	60 BPM

Calibration Function Keys

An NAD Omicron monitor has three separate calibration operations; "21% O_2 Calibration Operation" on page 3-8, "100% O_2 Calibration Operation" on page 3-8, and "Pressure and Flow Calibration Operation" on page 3-8. To prevent accidental or unexpected interruption of respiratory monitoring that occurs during calibration, you must confirm that you intend to calibrate the instrument. To do this, you must press and hold any of the calibration keys for at least 3 seconds. This starts the calibration sequence for that key's function. To initiate another calibration sequence, you must release all calibration keys for at least two seconds before pressing another calibration key.

21% O_2 Calibration Operation

Follow these steps to execute the 21% Calibration Operation:

1. Expose the oxygen sensor to room air for at least 30 seconds.
2. Press the 21% O2 Cal key for three seconds to begin the oxygen calibration.
   After three seconds, the monitor will display CALIBRATE, which indicates that it has completed room oxygen calibration.

100% O_2 Calibration Operation

Follow these steps to execute the 100% Calibration Operation:

1. Expose the oxygen sensor to a gas environment of 100% oxygen for at least 60 seconds.
2. Press the 100% 02 Cal key for three seconds to begin the second part of the oxygen calibraton.
   After three seconds, the monitor will display CALIBRATE, which indicates it has completed the 100% oxygen calibration.

Pressure and Flow Calibration Operation

When the monitor is first energized, it will display pressure and volume parameters even though you have not initiated a zero calibration. Without performing a flow calibration, the monitor may not achieve its specified accuracy. After 15 minutes, the monitor will display FLOW CAL to remind you to perform a zero calibration.

The following steps describe the Pressure and Flow Calibration Operation:

1. Pressing the Flow Cal key for three seconds starts a calibration process that sets zero values for both the pressure and flow channels. It is used to reduce measurement inaccuracies due to temperature drift or other external environmental variations.
2. To ensure flow accuracy, reduce the air flow to a minimum and remove the patient hose at the exhalation valve. Turn the ventilator off and minimize any movement of the patient or the monitor hoses.
3. When the calibration process starts, the monitor will display CALIBRATE while it establishes the zero set point for the pressure channel.

4. After the pressure calibration is complete, the monitor will display PRESS OK and 0000.
5. Within three seconds, the monitor will display FLOW OK and 0000, indicating that it is establishing the zero set points for the two flow channels (Plus and Minus Flow).
6. After the tidal volume calibration is complete, the monitor will display TIDAL VOL and ----.
7. Finishing this sequence indicates that the monitor has successfully completed both pressure and tidal volume zero calibrations and will achieve pressure and volume accuracy specifications.

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Cleaning and Sterilizing

This section describes how to clean and sterilize the NAD Omicron Monitor.

User Responsibilities

The frequency, level, and need for disinfection of the NAD Omicron Monitor and its accessories are determined by your facility based on the conditions of use and hospital infection control policy.

If disinfection is required, first clean, dry, and then disinfect the monitor and its parts according to the guidelines provided in this chapter. Determining the need and frequency of cleaning or disinfecting any particular component is the responsibility of the your facility. These procedures should be performed according to procedures established by your facility, following the specific instructions provided by the manufacturer of the disinfection equipment or agent used.

For additional information about infection control practice, refer to the *APIC Guideline for the Selection and Use of Disinfectants*. This guideline was developed by the Association for Professionals in Infection Control and Epidemiology, Inc. and published in AJIC Vol. 24, No. 4, pp. 313-342, August 1996.

When necessary, decontamination procedures should be carried out at the conclusion of each patient's use of the monitor. Institutional, JCAHO, and OSHA standards must be followed at all times. It is your responsibility to validate any deviation from manufacturer's prescribed cleaning and sterilization instructions as to efficacy and appropriateness. Any questions concerning these Instructions may be directed to:

Technical Support
North American Drager
3135 Quarry Road
Telford, PA 18969
1-215-721-5400

Pre-Processing

When removing the Omicron Monitor from patient care use, the flow head, pressure tubing, and ventilator circuit must be transported in a non-permeable, sealed plastic bag. In the event that any component has been contaminated by blood, a red hazardous material bag must be used.

Omicron Monitor

Clean the case containing the monitor with mild detergent and water. Follow up with a 70% to 90% diluted solution of ethyl or isopropyl alcohol or sodium hypochlorite (5.2% household bleach) at 1:500 dilution (100 ppm chlorine). Care should be maintained to avoid contact with the LCD screen as exposure to liquid disinfectants will alter screen integrity.

Flow Head

Prior to disinfection, remove the pressure tubing from the flow head. Clean dirt debris and extraneous matter from the flow head by means of a soap and water solution. This can be accomplished through hand washing, use of a mechanical washer, or ultrasonic bath.

All cleaning solution must be rinsed from the flow head after washing. All three pressure ports on the flow head should be flushed throughout with compressed gas (at a flowrate between 10 and 15 L/min) for sixty seconds each to ensure that the remaining solution is removed and that the ports are dry. The flow head must be completely dry of water to visual inspection. The recommended method is to use a properly filtered equipment dryer for the manufacturer's recommended time and temperature. This is necessary for sterilization procedures to be effective.

The recommended method of disinfection is a pulsing pre-vacuum, post vacuum steam sterilization cycle of 270°F (130°C) for four minutes. Proper packaging (heat sealed paper, transparent pouches) must be done prior to sterilization to prevent re-contamination of the flow head prior to use. Heat sensitive tape and biological indicators are mandated to ensure efficacy of the sterilization process.

The manufacturers recommended life of the flow head is 120 exposures to a sterilization cycle or one year, whichever comes first.

Triple Lumen Tubing

Clean dirt, debris, and extraneous matter from the pressure tubing by means of a soap and water solution. This can be accomplished through hand washing, use of a mechanical washer, or ultrasonic bath. All cleaning solution must be rinsed from the pressure tubing after washing. All three pressure ports on the flow head should be flushed throughout with compressed gas (at a flowrate between 10 and 15 L/min) for sixty seconds each to ensure that the remaining solution is removed and that the ports are dry. The flow head must be completely dry of water to visual inspection. The recommended method is to use a properly filtered equipment dryer for the manufacturer's recommended time and temperature. This is necessary for sterilization procedures to be effective.

The recommended method of sterilization is a pulsing pre-vacuum, post vacuum steam sterilization cycle of 270°F (130°C) for four minutes. Proper packaging (heat sealed paper, transparent pouches) must be completed prior to sterilization to prevent re-contamination of the flow head prior to use. Heat sensitive tape and biological indicators are mandated to ensure efficacy of the sterilization process.

As an alternative, the tubing may be disinfected using a 2% glutaraldehyde solution or using ethylene oxide gas (EtO). Soak the tubing in a 2% glutaraldehyde solution for more than 20 minutes. When using the EtO process, follow the manufacturer's guidelines.

Replace the pressure tubing after 20 exposures to a disinfection cycle or one year, whichever comes first.

5 Troubleshooting

This section describes how to troubleshoot NAD Omicron Monitor issues.

Faults and Actions

This section describes system faults and provides resolutions to correct these faults.

Questionable Pressure Accuracy

1. Disconnect the unit from the external tubing.
2. Verify that the pressure port is vented to atmosphere.
3. Turn the power on and verify that the zero pressure reading before FLOW CAL is less than 4 cm H_2O.
4. Press the FLOW CAL key and verify that the pressure reads zero.
5. Connect the unit in parallel to a pressure source with a high precision reference gauge (better than 0.1% FSO accuracy).
6. Apply pressure and verify the unit's accuracy. If it is still not within specification, disengage the unit, consult the manufacturer, and DO NOT CONTINUE TO USE THE MONITOR IN THE CLINICAL SETTING.

Inability to Set Pressure Low Limit Screen to Desired Value

Check the High Limit Screen setting and verify that it is greater than the desired Low Limit set value by at least 6 cm H_2O. If the difference equals or exceeds this value, consult the manufacturer and DO NOT CONTINUE TO USE THE MONITOR IN THE CLINICAL SETTING.

O_2 Sensor Failure

Check the sensor's electrical connection and repeat the calibration process. If the problem persists, change the oxygen sensor and recalibrate. If the problem remains, consult the manufacturer and DO NOT CONTINUE TO USE THE MONITOR IN THE CLINICAL SETTING.

Flow and Tidal Volume Measurement Error

Visually inspect the flow sensor tube and monitor to ensure that all pressure connections are intact. Recalibrate the monitor. If the problem persists, measure the exhaled volumes using a secondary source (i.e., a hand-held spirometer). If the measurement of the monitor is not within 14% of the volume of the spirometer, remove the monitor from clinical use for evaluation by a qualified service technician. If the problem persists under bench conditions, consult the manufacturer and DO NOT CONTINUE TO USE THE MONITOR IN THE CLINICAL SETTING.

Flow Pressure Data is Missing Throughout Mechanical Ventilation

The probable cause for the flow pressure to be missing throughout the mechanical ventilation is that the Pressure Low Limit is set too high. Adjust the Pressure Low Limit to about 4 cm H_2O below the peak pressure value.

If a breathing pressure of more than fifty (50) cm H_2O above the current peak pressure values was detected, it is necessary to perform a flow calibration or to power cycle the anesthesia machine to clear the alarm.

WARNING: If the NAD Omicron Monitor shows a reading of 127 cm H_20 or -127 cm H_2O, DO NOT CONTINUE TO USE THE MONITOR IN THE CLINICAL SETTING. Remove the unit from use for servicing.

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6 Specifications

This section provides the NAD Omicron Monitor specifications.

General

The following is general specification information:

System Resolution 12 Bit

Information Display 2.75 inch circular back lit, high contrast LCD display with analog and digital representation.

Pressure

The following is general pressure specification information:

Pressure Transducer Type Temperature compensated piezo-resistive, differential pressure transducer

Transducer Measurement Range -120 to +120 cm H_2O (with 2x over pressure protection)

Accuracy 1.5% FSO (best fit straight line at 0 to 50C)

Data Sampling 10 ms (20 ms below 50 BPM)

FI02

The following is FI02 specification information:

Transducer Type Dual Galvanic Electrochemical Cells

Transducer Measurement Range 0 - 100% O_2

Displayed Range 0 - 100% O_2

Accuracy 3.0 % Full Scale Output (two point calibration mode)

5.0% Full Scale Output (one point calibration mode)

Flow

The following is Flow specification information:

Transducer Type Pitot tube incorporated into reusable flow tube.

Accuracy Better than 5.0% Full Scale Output if O_2 sensor employed

Displayed Information

The following is monitor display specification information:

Pressure Range

- Operating Range: -10 to +120 cm H_2O
- Display Range:
  - -10 to + 120 cm H_2O. Peak
  - -10 to + 120 cm H_2O. Mean
  - -10 to + 120 cm H_2O. PEEP
- Resolution:
  - 1.0 cm H_2O on bar graph display
  - 0.1 cm H_2O on numeric display

Respiratory Rate

- Operating Range: 2 to 400 BPM
- Display Range: 2 to 400 BPM
- Resolution: 0.1 BPM on numeric display

FIO_2

- Operating Range: 18% to 100%
- DisplayRange: 0% to 100%
- Resolution: 0.1% on numeric display
- (O_2 SENSOR in case of O_2 Sensor Failure)

Tidal Volume

- Operating Range: 0-2500 mL
- Display Range: 50-2500 mL
- Resolution: 1 mL on numeric display
- (FLOW SENS - in case of Flow Sensor Failure)

Minute Volume

- Operating Range: 0-80 L
- Display Range: 0-80 L
- Resolution- 0.1 L on numeric display
- (FLOW SENS - in case of Flow Sensor Failure)

Environmental

The following is environmental information.

Operating

Temperature	50° F to 95° F
Humidity	30% to 75% (non-condensing)

Storage

Temperature	14° F to 122° F
Humidity	10% to 90% (non-condensing)

User Adjustable Alarm Limits

The following displays the user adjustable alarm limits specification information:

Table 1. User Adjustable Alarm Limits

Alarm Limit Type	Alarm Limit Value
Pressure High Limit	+11 to +120 cm H_2O (Resolution 1 cmH_2O)
Pressure Low Limit	+5 to +114 cm H_2O (Resolution 1 cmH_2O)
O_2 High Limit	25% to 99% 100% = High Alarm Disabled (Resolution 1%)
O_2 Low Limit	18% to 95% (Resolution 1%)
Total Respiratory Rate High Limit	5 to 250 BPM (Resolution 5 BPM)
Tidal Volume Low Limit	50 to 2400 mL (Resolution 50 mL)
Tidal Volume High Limit	150 to 2500 mL (Resolution 50 mL)
Minute Volume Low Limit	0 to 79 L (Resolution 1 L)
Minute Volume High Limit	1 to 80 L (Resolution 1 L)

Other Functions

System Self Test

Automatic upon power-up

Alarm Disable

First 60 seconds after power-up (excluding High Pressure Alarm and O_2 alarm).

Dräger Medical

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